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09/678,434	10/03/2000	John McNeil	IBIS-0312	5282

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EXAMINER

QUAN, ELIZABETH S

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 08/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/678,434

Applicant(s)

MCNEIL, JOHN

Examiner

Elizabeth Quan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 and 31-35 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 18-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-17, 23-28 and 31-35 is/are rejected.
- 7) ☒ Claim(s) 11-13 is/are objected to.
- 8) ☒ Claim(s) 1-28 and 31-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, Species 2 consisting of claims 1-8, 10-17, 23-28, and 31-35 in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Objections

2. Claims 11-13 objected to because of the following informalities: "is reproducibly". Appropriate correction is required. For examining purposes, the limitation has been interpreted as the dispensing mechanism can reproduce in volume for each dispensed measured quantity of sample to an accuracy of about 5 microliters, 1 microliters, and/or 0.5 microliters.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 1-3, 17, 23, 31, 34, 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Referring to claims 1, 2, and 31, the storage devices in claims 1 and 2 appear to store samples to be dispensed, such that each well of the plate has a corresponding dispensing mechanism. However, in claim 31, the first storage device contains the liquids to be dispensed into the second storage device. This is confusing. The second storage device cannot possibly have wells each corresponding to a dispensing mechanism.

6. Referring to claim 23, it is unclear whether the filter is actually disposed between the storage device and dispensing mechanism. From the drawings it appears the filter is within the storage device of which the dispensing mechanism is part of.

7. Referring to claim 34, the robots can locate themselves and the storage devices? Do the robots dispense too? It is not known what is meant by this claim. For examining purposes, the limitation has been interpreted as the robots can locate themselves and the storage devices, which would be inherent or intrinsic if claim 32 is met by prior art.

8. Claim 35 provides for the use of the self-dispensing storage devices, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 35 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1, 6, 17, 23, 25, 31, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,461,328 to Kenney.

Referring to claims 1, 6, 17, 23, 25, 31, 33, Kenney discloses a self-dispensing system for transferring samples from one self-dispensing storage device (3) to another self-dispensing storage device (8) or a work station (see FIGS. 2, 4, 5, and 10). A first self-dispensing storage device comprises a storage device (30) with one or more reservoirs (4) for holding a sample to be dispensed (see FIGS. 2, 4, 5, and 10). One or more corresponding dispensing mechanisms are connected to and in dispensing communication with each of the one or more reservoirs of the storage device (3) through at least one opening in the reservoir (see FIGS. 2, 4, 5, and 10). A second self-dispensing storage device comprises a storage device (8) with one or more reservoirs for holding a sample to be dispensed (see FIGS. 2, 4, 5, and 10). One or more corresponding dispensing mechanisms are connected to and in dispensing communication with each of the one or more reservoirs of the storage device (8) through at least one opening in the reservoir (see FIGS. 4, 4a; COL. 14, lines 21-38). A driving mechanism drives the dispensing mechanism of the first self-dispensing storage device (see COL. 2, lines 50-55). A precise and reproducible measured volume of the sample is dispensed from one or more reservoirs of the first self-dispensing storage device to the one or more reservoirs of the second self-dispensing storage device (see FIGS. 2, 4, 5, and 10). The storage device (3) is a multi-well plate with each of the wells having a corresponding dispensing mechanism (see FIGS. 2, 4, 5, and 10). The storage device and dispensing mechanism

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are disposable after the sample has been completely dispensed. A filter (22) is disposed between the storage device and dispensing mechanism. Since Applicant has not provided the structure of a cow udder, Examiner has defined a projection as a cow udder type of dispensing mechanism. In this case, the projections (4) is characterized as cow udder types of dispensing mechanism. Therefore, Kenney includes all the limitations in claims 1, 6, 17, 23, 25, 31, 33.

11. Claims 1-4, 6, 7, 11-13, 24, 25, 27, 31, 35 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,083,763 to Balch.

Referring to claims 1-4, 6, 7, 11-13, 24, 25, 27, 31, 35, Balch discloses a self-dispensing system for transferring samples from one self-dispensing storage device to another self-dispensing storage device or a work station (see FIGS. 4, 4a). A first self-dispensing storage device comprises a storage device with one or more reservoirs for holding a sample to be dispensed (see FIGS. 4, 4a). One or more corresponding dispensing mechanisms are connected to and in dispensing communication with each of the one or more reservoirs of the first storage device through at least one opening in the reservoir (see FIGS. 4, 4a; COL. 14, lines 21-38). A second self-dispensing storage device comprises a storage device with one or more reservoirs for holding a sample to be dispensed (see FIGS. 4, 4a). One or more corresponding dispensing mechanisms are connected to and in dispensing communication with each of the one or more reservoirs of the second storage device through at least one opening in the reservoir (see FIGS. 4, 4a; COL. 14, lines 21-38). A driving mechanism drives the dispensing mechanism of the first self-dispensing storage device (see COL. 12, lines 19-35). A precise and

reproducible measured volume of the sample is dispensed from one or more reservoirs of the first self-dispensing storage device to the one or more reservoirs of the second self-dispensing storage device (see FIGS. 4, 4a; COL. 9, lines 11-55; COL. 14, lines 21-38). The first storage device is a multi-well plate with each of the wells having a corresponding dispensing mechanism (see FIGS. 4, 4a; COL. 9, lines 11-55; COL. 14, lines 21-38). The wells appear to be evenly spaced (see FIGS. 4, 4a). The microtiter plate may have 24, 96, 384, or 1536 wells (see COL. 9, lines 11-23; COL. 14, lines 21-38). The storage device and dispensing mechanism are disposable after the sample has been completely dispensed. Since the dispensing mechanism can deliver picoliter and nanoliter amounts of fluid accurately and precisely, it would appear that the dispensing mechanism can deliver a measured quantity to an accuracy of about 5 microliters, 1 microliter, and 0.5 microliter. It is inherent that the storage device and its sample are freezable to at least about -20 degrees Celsius and capable of being thawed. Since liquids are being delivered to at least one reaction vessel, the driving mechanism is activating one or more of the dispensing mechanism corresponding to the first storage device. Inherently there is a controller for initiating the dispensing opening of the sample. The storage devices maybe used in anywhere, including pharmaceutical research laboratory. Given the right pressure, any reservoir is capable of collapsing or breaking down by changing shape or size. Therefore, Balch includes all the limitations in claims 1-4, 6, 7, 11-13, 24, 25, 27, 31, 35.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 5, 8, 11-14, 28, 32, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,083,763 to Balch.

Referring to claim 5, Balch does not address the spacing or capacity of the wells. However, it is very well known that microtiter plates come in a variety of sizes with different well spacing to conform to automation and variety of capacities for dealing with a certain amount of samples, reactants, reagents, and generated products. Furthermore, it would have been obvious to one having ordinary skill in the art to modify the dimensions of the microtiter plate in order to conform to automation and deal with different amounts of samples, reactants, reagents, or generated products. It was held that difference in dimensions is not a patentable distinction (*Gardner v. TEC Systems, Inc.*, 725 F.2d 1338,

220 USPQ 777 (Fed. Cir 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984)) and discovering an optimum value of a result effective variable involves only routine skill in the art (*In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)).

Referring to claim 8, it appears that the storage device comprises a semi-rigid reservoir such that it is sufficiently durable to hold liquids. Balch does not explicitly disclose a dispensed volume replacement; however, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a dispensed volume replacement, such as a person or robot delivering liquids via a pipette or an automated delivery system delivering liquids, in the apparatus of Balch to replenish liquids to perform subsequent procedures or assays.

Referring to claims 11-14, Balch does not explicitly disclose the dispensing mechanism dispensing measured quantity of the sample to an accuracy of 5 microliters, 1 microliter, 0.1 microliter, or 0.5 microliter. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Balch to provide the capability of dispensing to the above accuracies as necessary to handle a certain amount of samples, reactants, reagents, and generated products in performing certain assays.

Referring to claims 28, 32, 34, Balch does not disclose one or more robots positioning the storage device with respect to another storage device. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide one or more robots in Balch to efficiently and automatically position the storage devices with respect to each other such that the dispensing mechanism is operable

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between the two with easy and convenient access between the two. In order for the robot to position the storage devices they must be able to locate themselves as well as the storage devices.

15. Claims 10, 15, 16, 26 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,083,763 to Balch in view of WO 98/04358 to Tisone et al.

Referring to claims 10, 15, 16, 26, Balch does not disclose a positive displacement type of dispensing mechanism with inlet and outlet valves, actuators with suction and discharge stroke, and the driving mechanism internal to the dispensing mechanism. Tisone discloses such a configuration to precisely dispense droplets with a desired flow rate, droplet size, mist quality, droplet frequency, and/or droplet velocity (see ABSTRACT). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Balch to provide a positive displacement type of dispensing mechanism with inlet and outlet valves, actuators with suction and discharge stroke, and the driving mechanism internal to the dispensing mechanism as in Tisone et al. to precisely dispense droplets with a desired flow rate, droplet size, mist quality, droplet frequency, and/or droplet velocity.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. They include one or more limitations in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The examiner can normally be reached on M-F (8:00-4:30).


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Elizabeth Quan
Examiner
Art Unit 1743

eq
August 11, 2003


Jill Warden
Supervisory Patent Examiner
Technology Center 1700